

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: FEED

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Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
Male							
Southern Research Institute	059902703	08/12/02	729	50(3)	37(705)	452.8	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517405	08/05/02	729	50(3)	33(703)	510.0	Cresols
Southern Research Institute	059900705	04/21/03	729	50(3)	33(679)	460.9	Goldenseal root powder
Southern Research Institute	052000803	03/04/03	729	50(3)	36(704)	452.1	Milk thistle extract
Female							
Southern Research Institute	059902703	08/12/02	733	50(5)	36(702)	314.7	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517405	N/A	N/A	0(0)	0(0)	N/A	Cresols
Southern Research Institute	059900705	04/21/03	731	50(5)	30(699)	326.0	Goldenseal root powder
Southern Research Institute	052000803	03/04/03	732	50(5)	38(693)	328.4	Milk thistle extract

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		Male			Female		
#All Organs:							
Benign Tumors							
		49/50 (98%)	50/50 (100%)	47/50 (94%)	45/50 (90%)	46/50 (92%)	
		50/50 (100%)			39/50 (78%)		
Overall Incidence	Total	196/200 (98%)	Mean 98%	SD 2.83%	Total 130/150 (86.67%)	Mean 86.67%	SD 7.57%
.....							
#All Organs:							
Malignant Tumors							
		27/50 (54%)	23/50 (46%)	29/50 (58%)	15/50 (30%)	19/50 (38%)	
		26/50 (52%)			18/50 (36%)		
Overall Incidence	Total	105/200 (52.5%)	Mean 52.5%	SD 5%	Total 52/150 (34.67%)	Mean 34.67%	SD 4.16%
.....							
#All Organs:							
Malignant and Benign Tumors							
		50/50 (100%)	50/50 (100%)	50/50 (100%)	47/50 (94%)	48/50 (96%)	
		50/50 (100%)			46/50 (92%)		
Overall Incidence	Total	200/200 (100%)	Mean 100%	SD 0%	Total 141/150 (94%)	Mean 94%	SD 2%
.....							
#All Organs:							
Hemangioma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)			0/50 (0%)		
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
#All Organs:							
Hemangiosarcoma							
		2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)			0/50 (0%)		
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total 0/150 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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		Male				Female			
#All Organs:									
Hemangiosarcoma or Hemangioma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Histiocytic Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)		1/50 (2%)	
		3/50 (6%)				0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 3%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	
.....									
#All Organs:									
Leukemia: Erythrocytic									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#All Organs:									
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated									
		19/50 (38%)	15/50 (30%)	21/50 (42%)		9/50 (18%)		9/50 (18%)	
		17/50 (34%)				6/50 (12%)			
Overall Incidence	Total	72/200 (36%)	Mean 36%	SD 5.16%	Total	24/150 (16%)	Mean 16%	SD 3.46%	
.....									
#All Organs:									
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	

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		Male				Female			
#All Organs:									
Mesothelioma: Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Mesothelioma: Benign, Malignant, NOS									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Mesothelioma: Malignant									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Osteoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%	

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#: Denominator is number of animals necropsied

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		Male				Female			
#All Organs:									
Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Cortex:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)		1/50 (2%)	
		2/50 (4%)				0/48 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	3/148 (2.03%)	Mean 2%	SD 2%	
.....									
*Adrenal Cortex:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla:									
Ganglioneuroma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)		0/48 (0%)	
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)		0/48 (0%)	
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%	

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		Male				Female			
*Adrenal Medulla:									
Pheochromocytoma Benign									
		8/50 (16%)	8/50 (16%)	5/49 (10%)		1/50 (2%)		0/48 (0%)	
		5/50 (10%)				1/48 (2%)			
Overall Incidence	Total	26/199 (13.07%)	Mean 13.05%	SD 3.41%	Total	2/146 (1.37%)	Mean 1.36%	SD 1.18%	
.....									
*Adrenal Medulla:									
Pheochromocytoma Complex									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)		0/48 (0%)	
		1/50 (2%)				1/48 (2%)			
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/146 (0.68%)	Mean 0.69%	SD 1.2%	
.....									
*Adrenal Medulla:									
Pheochromocytoma Malignant									
		3/50 (6%)	0/50 (0%)	1/49 (2%)		2/50 (4%)		0/48 (0%)	
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 2.83%	Total	2/146 (1.37%)	Mean 1.33%	SD 2.31%	
.....									
*Adrenal Medulla:									
Pheochromocytoma: Benign, Complex, Malignant, NOS									
		11/50 (22%)	8/50 (16%)	6/49 (12%)		3/50 (6%)		0/48 (0%)	
		6/50 (12%)				2/48 (4%)			
Overall Incidence	Total	31/199 (15.58%)	Mean 15.56%	SD 4.67%	Total	5/146 (3.42%)	Mean 3.39%	SD 3.07%	
.....									
#Bone:									
Chondrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

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		Male				Female			
#Bone:									
Chondrosarcoma or Chondroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Chordoma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Osteoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/150 (0%)	Mean 0%	SD 0%	

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		Male				Female			
*Brain:									
Astrocytoma Malignant									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Ependymoma Benign									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Ependymoma Malignant									
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Glioma Malignant									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Granular Cell Tumor Benign									
		2/50 (4%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%	

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#: Denominator is number of animals necropsied

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		Male				Female			
*Brain:									
Medulloblastoma Mal									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Oligodendroglioma Benign									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Oligodendroglioma Malignant									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
*Brain:									
Oligodendroglioma, Glioma, or Astrocytoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
*Brain:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

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		Male				Female			
*Brain:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Clitoral/Preputial Gland:									
Adenoma									
		1/50 (2%)	5/50 (10%)	0/50 (0%)		10/50 (20%)	5/50 (10%)		
		1/50 (2%)				11/50 (22%)			
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 4.43%	Total	26/150 (17.33%)	Mean 17.33%	SD 6.43%	
.....									
*Clitoral/Preputial Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	4/50 (8%)		
		2/50 (4%)				3/50 (6%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.31%	Total	7/150 (4.67%)	Mean 4.67%	SD 4.16%	
.....									
*Clitoral/Preputial Gland:									
Carcinoma or Adenoma									
		1/50 (2%)	5/50 (10%)	2/50 (4%)		10/50 (20%)	9/50 (18%)		
		3/50 (6%)				14/50 (28%)			
Overall Incidence	Total	11/200 (5.5%)	Mean 5.5%	SD 3.42%	Total	33/150 (22%)	Mean 22%	SD 5.29%	
.....									
*Clitoral/Preputial Gland:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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		Male				Female			
*Clitoral/Preputial Gland:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Ear:									
Neural Crest Tumor									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Esophagus:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Esophagus:									
Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Eye:									
Melanoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
#Eye:									
Schwannoma Malignant									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Harderian Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Harderian Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Heart:									
Schwannoma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Heart:									
Schwannoma Malignant									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: FEED

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		Male				Female			
#Intestine Large: Colon/Rectum:									
Adenoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Large: Colon/Rectum:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Large: Colon/Rectum:									
Carcinoma or Adenoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Large: Colon/Rectum:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Duodenum:									
Carcinoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: FEED

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		Male				Female			
#Intestine Small: Duodenum:									
Leiomyoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Ileum:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Jejunum:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Jejunum:									
Granular Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Jejunum:									
Leiomyoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: FEED

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 Report Date: 03/20/2010

		Male				Female			
#Intestine Small: Jejunum:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified:									
Carcinoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified:									
Carcinoma or Adenoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified:									
Granular Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
#Intestine Small: Site Unspecified:									
Leiomyoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Islets, Pancreatic:									
Adenoma									
		1/50 (2%)	1/49 (2%)	7/50 (14%)		2/49 (4%)		0/49 (0%)	
		3/50 (6%)				0/48 (0%)			
Overall Incidence	Total	12/199 (6.03%)	Mean 6.01%	SD 5.65%	Total	2/146 (1.37%)	Mean 1.36%	SD 2.36%	
.....									
*Islets, Pancreatic:									
Carcinoma									
		1/50 (2%)	1/49 (2%)	0/50 (0%)		0/49 (0%)		0/49 (0%)	
		1/50 (2%)				0/48 (0%)			
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	0/146 (0%)	Mean 0%	SD 0%	
.....									
*Islets, Pancreatic:									
Carcinoma or Adenoma									
		2/50 (4%)	2/49 (4%)	7/50 (14%)		2/49 (4%)		0/49 (0%)	
		4/50 (8%)				0/48 (0%)			
Overall Incidence	Total	15/199 (7.54%)	Mean 7.52%	SD 4.71%	Total	2/146 (1.37%)	Mean 1.36%	SD 2.36%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
*Kidney: Pelvis and Transitional Epithelium: Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/47 (0%)		0/49 (0%)	
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/144 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/47 (0%)		0/49 (0%)	
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/144 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Pelvis and Transitional Epithelium: Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)		0/49 (0%)	
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)		0/49 (0%)	
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)		0/49 (0%)	
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: FEED

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		Male				Female			
*Kidney: Renal Tubule: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)		
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)		
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)		
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Mesenchymal Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)		
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Mesenchymal Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)		
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: FEED

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		Male				Female			
*Kidney: Renal Tubule:									
 Nephroblastoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)		0/49 (0%)	
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule:									
 Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)		1/49 (2%)	
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/144 (0.69%)	Mean 0.68%	SD 1.18%	
.....									
*Liver:									
 Cholangioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
 Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
 Hepatocellular Adenoma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)		0/50 (0%)	
		3/50 (6%)				2/50 (4%)			
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
*Liver:									
Hepatocellular Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Hepatocellular Carcinoma or Hepatoblastoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Hepatocellular Carcinoma or Hepatocellular Adenoma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)		0/50 (0%)	
		3/50 (6%)				2/50 (4%)			
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	
.....									
*Liver:									
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)		0/50 (0%)	
		3/50 (6%)				2/50 (4%)			
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	
.....									
*Liver:									
Ito Cell Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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 Report Date: 03/20/2010

		Male				Female			
*Lung:									
Alveolar/Bronchiolar Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/50 (2%)		
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)		
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	1/50 (2%)		
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	3/150 (2%)	Mean 2%	SD 0%	
.....									
*Lung:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Lung:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
*Lung:									
Squamous Cell Carcinoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Mammary Gland:									
Adenolipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Mammary Gland:									
Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)		2/50 (4%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	3/150 (2%)	Mean 2%	SD 2%	
.....									
#Mammary Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		4/50 (8%)	
		0/50 (0%)				4/50 (8%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	8/150 (5.33%)	Mean 5.33%	SD 4.62%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
#Mammary Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)		6/50 (12%)	
		0/50 (0%)				4/50 (8%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	11/150 (7.33%)	Mean 7.33%	SD 5.03%	
.....									
#Mammary Gland:									
Fibroadenoma									
		2/50 (4%)	0/50 (0%)	1/50 (2%)		29/50 (58%)		30/50 (60%)	
		0/50 (0%)				28/50 (56%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	87/150 (58%)	Mean 58%	SD 2%	
.....									
#Mammary Gland:									
Fibroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma or Adenoma									
		2/50 (4%)	1/50 (2%)	1/50 (2%)		30/50 (60%)		30/50 (60%)	
		0/50 (0%)				28/50 (56%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	88/150 (58.67%)	Mean 58.67%	SD 2.31%	
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma, Carcinoma, or Adenoma									
		2/50 (4%)	1/50 (2%)	1/50 (2%)		30/50 (60%)		31/50 (62%)	
		0/50 (0%)				28/50 (56%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	89/150 (59.33%)	Mean 59.33%	SD 3.06%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
#Mesentery:									
Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Hemangiosarcoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Lipoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Nose:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: FEED

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		Male				Female			
*Nose:									
Chondroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Nose:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Papilloma Squamous or Papilloma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
#Oral Mucosa:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Oral Mucosa:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Ovary:									
Cystadenoma									
						0/50 (0%)		0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Ovary:									
Granulosa Cell Tumor Benign									
						0/50 (0%)		0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Ovary:									
Granulosa Cell Tumor Malignant									
						0/50 (0%)		0/50 (0%)	
						2/50 (4%)			
Overall Incidence	Total				Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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				Male					Female
*Ovary:									
Granulosa Cell Tumor: Benign, Malignant, NOS									
						0/50 (0%)		0/50 (0%)	
						2/50 (4%)			
Overall Incidence				Total	2/150 (1.33%)		Mean 1.33%		SD 2.31%
.....									
*Ovary:									
Granulosa-Theca Tumor Benign									
						1/50 (2%)		0/50 (0%)	
						0/50 (0%)			
Overall Incidence				Total	1/150 (0.67%)		Mean 0.67%		SD 1.15%
.....									
*Ovary:									
Granulosa-Theca Tumor Malignant									
						0/50 (0%)		0/50 (0%)	
						0/50 (0%)			
Overall Incidence				Total	0/150 (0%)		Mean 0%		SD 0%
.....									
*Ovary:									
Tubulostromal Adenoma									
						0/50 (0%)		0/50 (0%)	
						0/50 (0%)			
Overall Incidence				Total	0/150 (0%)		Mean 0%		SD 0%
.....									
*Pancreas:									
Adenoma									
		0/49 (0%)	0/49 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	
		2/50 (4%)					0/48 (0%)		
Overall Incidence	Total	2/198 (1.01%)	Mean 1%	SD 2%	Total	0/146 (0%)	Mean 0%		SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
*Pancreas:									
Carcinoma									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)		
		0/50 (0%)				0/48 (0%)			0/49 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%	
.....									
*Pancreas:									
Carcinoma or Adenoma									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)		
		2/50 (4%)				0/48 (0%)			0/49 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1%	SD 2%	Total	0/146 (0%)	Mean 0%	SD 0%	
.....									
*Pancreas:									
Mixed Tumor Benign									
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)		
		0/50 (0%)				0/48 (0%)			0/49 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%	
.....									
*Pancreas:									
Mixed Tumor Malignant									
		0/49 (0%)	0/49 (0%)	1/50 (2%)		0/49 (0%)	0/49 (0%)		
		0/50 (0%)				0/48 (0%)			0/49 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total	0/146 (0%)	Mean 0%	SD 0%	
.....									
*Parathyroid Gland:									
Adenoma									
		1/45 (2%)	1/46 (2%)	0/49 (0%)		0/48 (0%)	0/49 (0%)		
		0/50 (0%)				0/49 (0%)			0/49 (0%)
Overall Incidence	Total	2/190 (1.05%)	Mean 1.1%	SD 1.27%	Total	0/146 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Adenoma									
		10/50 (20%)	20/50 (40%)	8/50 (16%)		24/49 (49%)		25/50 (50%)	
		13/50 (26%)				20/50 (40%)			
Overall Incidence	Total	51/200 (25.5%)	Mean 25.5%	SD 10.5%	Total	69/149 (46.31%)	Mean 46.33%	SD 5.5%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%)		0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/149 (1.34%)	Mean 1.35%	SD 1.17%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma or Adenoma									
		10/50 (20%)	20/50 (40%)	8/50 (16%)		25/49 (51%)		25/50 (50%)	
		13/50 (26%)				21/50 (42%)			
Overall Incidence	Total	51/200 (25.5%)	Mean 25.5%	SD 10.5%	Total	71/149 (47.65%)	Mean 47.67%	SD 4.94%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Ganglioneuroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%	
.....									
*Pituitary Gland: Pars Intermedia:									
Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/149 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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 Report Date: 03/20/2010

		Male				Female			
*Pituitary Gland: Pars Intermedia:									
Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/149 (0%)	Mean 0%	SD 0%	
.....									
*Pituitary Gland: Pars Nervosa:									
Craniopharyngioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%	
.....									
*Prostate:									
Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)					
		0/50 (0%)							
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%					
.....									
*Prostate:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)					
		0/50 (0%)							
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%					
.....									
*Salivary Glands:									
Carcinoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/48 (0%)				0/50 (0%)			
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: FEED

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		Male				Female			
*Salivary Glands:									
 Carcinoma or Adenoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/48 (0%)				0/50 (0%)			
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Salivary Glands:									
 Sarcoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/48 (0%)				0/50 (0%)			
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Salivary Glands:									
 Schwannoma Malignant									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/48 (0%)				0/50 (0%)			
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Seminal Vesicle:									
 Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)							
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%					
.....									
#Skeletal Muscle:									
 Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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 Report Date: 03/20/2010

		Male				Female			
#Skeletal Muscle:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skeletal Muscle:									
Rhabdomyosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skeletal Muscle:									
Rhabdomyosarcoma or Rhabdomyoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Adenoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Adenoma or Basosquamous Tumor Benign									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: FEED

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		Male				Female			
#Skin:									
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Skin:									
Basal Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Skin:									
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma									
		4/50 (8%)	1/50 (2%)	2/50 (4%)		0/50 (0%)		1/50 (2%)	
		6/50 (12%)				1/50 (2%)			
Overall Incidence	Total	13/200 (6.5%)	Mean 6.5%	SD 4.43%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: FEED

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		Male				Female			
#Skin:									
Fibroma									
		4/50 (8%)	1/50 (2%)	5/50 (10%)		0/50 (0%)		1/50 (2%)	
		3/50 (6%)				1/50 (2%)			
Overall Incidence	Total	13/200 (6.5%)	Mean 6.5%	SD 3.42%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	
.....									
#Skin:									
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma									
		4/50 (8%)	4/50 (8%)	5/50 (10%)		0/50 (0%)		3/50 (6%)	
		4/50 (8%)				1/50 (2%)			
Overall Incidence	Total	17/200 (8.5%)	Mean 8.5%	SD 1%	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	
.....									
#Skin:									
Fibrosarcoma									
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Skin:									
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma									
		0/50 (0%)	3/50 (6%)	0/50 (0%)		0/50 (0%)		2/50 (4%)	
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.83%	Total	3/150 (2%)	Mean 2%	SD 2%	
.....									
#Skin:									
Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
#Skin:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Keratoacanthoma									
		3/50 (6%)	1/50 (2%)	2/50 (4%)		0/50 (0%)		0/50 (0%)	
		4/50 (8%)				0/50 (0%)			
Overall Incidence	Total	10/200 (5%)	Mean 5%	SD 2.58%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Lipoma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Liposarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
#Skin:									
Neural Crest Tumor									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Skin:									
Neural Crest Tumor, Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Neurofibroma or Schwannoma benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Neurofibrosarcoma or Schwannoma (malignant or NOS)									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: FEED

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		Male				Female			
#Skin:									
Sarcoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)		2/50 (4%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	
.....									
#Skin:									
Schwannoma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Skin:									
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		2/50 (4%)				1/50 (2%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
#Skin:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma or Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
		3/50 (6%)	1/50 (2%)	2/50 (4%)		0/50 (0%)		0/50 (0%)	
		6/50 (12%)				1/50 (2%)			
Overall Incidence	Total	12/200 (6%)	Mean 6%	SD 4.32%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
		3/50 (6%)	1/50 (2%)	2/50 (4%)		0/50 (0%)		0/50 (0%)	
		5/50 (10%)				0/50 (0%)			
Overall Incidence	Total	11/200 (5.5%)	Mean 5.5%	SD 3.42%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Trichoepithelioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
#Skin: Sebaceous Gland:									
Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		0/50 (0%)
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0% SD 0%
.....									
#Skin: Sebaceous Gland:									
Carcinoma or Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		0/50 (0%)
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0% SD 0%
.....									
#Spinal Cord:									
Astrocytoma Benign									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		0/50 (0%)
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0% SD 0%
.....									
#Spinal Cord:									
Astrocytoma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		0/50 (0%)
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0% SD 0%
.....									
#Spinal Cord:									
Glioma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		0/50 (0%)
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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 Report Date: 03/20/2010

		Male				Female			
*Spleen:									
Fibrosarcoma									
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
Fibrous Histiocytoma									
		0/50 (0%)	0/49 (0%)	1/49 (2%)		0/50 (0%)	0/49 (0%)	0/49 (0%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/148 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
Hemangiosarcoma									
		1/50 (2%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total	0/148 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
Leiomyosarcoma									
		1/50 (2%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total	0/148 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
Sarcoma									
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%	SD 0%	

#: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
#Stomach, Forestomach:									
Leiomyosarcoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma or Papilloma Squamous									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Stomach, Forestomach:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Stomach, Glandular:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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 Report Date: 03/20/2010

		Male				Female			
#Stomach, Glandular:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Glandular:									
Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Glandular:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Testes:									
Adenoma									
		46/50 (92%)	49/50 (98%)	42/50 (84%)					
		46/50 (92%)							
Overall Incidence	Total	183/200 (91.5%)	Mean 91.5%	SD 5.74%					
.....									
*Testes:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)							
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%					

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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 Report Date: 03/20/2010

		Male				Female			
*Thymus:									
Thymoma Benign									
		0/48 (0%)	0/47 (0%)	1/48 (2%)		0/46 (0%)		0/49 (0%)	
		0/41 (0%)				0/50 (0%)			
Overall Incidence	Total	1/184 (0.54%)	Mean 0.52%	SD 1.04%	Total	0/145 (0%)	Mean 0%	SD 0%	
.....									
*Thymus:									
Thymoma Malignant									
		0/48 (0%)	0/47 (0%)	0/48 (0%)		0/46 (0%)		0/49 (0%)	
		0/41 (0%)				0/50 (0%)			
Overall Incidence	Total	0/184 (0%)	Mean 0%	SD 0%	Total	0/145 (0%)	Mean 0%	SD 0%	
.....									
*Thymus:									
Thymoma NOS									
		0/48 (0%)	0/47 (0%)	0/48 (0%)		0/46 (0%)		0/49 (0%)	
		0/41 (0%)				0/50 (0%)			
Overall Incidence	Total	0/184 (0%)	Mean 0%	SD 0%	Total	0/145 (0%)	Mean 0%	SD 0%	
.....									
*Thymus:									
Thymoma: Benign, Malignant, NOS									
		0/48 (0%)	0/47 (0%)	1/48 (2%)		0/46 (0%)		0/49 (0%)	
		0/41 (0%)				0/50 (0%)			
Overall Incidence	Total	1/184 (0.54%)	Mean 0.52%	SD 1.04%	Total	0/145 (0%)	Mean 0%	SD 0%	
.....									
*Thyroid Gland: C-Cell:									
Adenoma									
		5/50 (10%)	6/50 (12%)	7/50 (14%)		3/49 (6%)		4/50 (8%)	
		5/48 (10%)				2/47 (4%)			
Overall Incidence	Total	23/198 (11.62%)	Mean 11.6%	SD 1.81%	Total	9/146 (6.16%)	Mean 6.13%	SD 1.87%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
*Thyroid Gland: C-Cell: Carcinoma									
		4/50 (8%)	1/50 (2%)	1/50 (2%)		1/49 (2%)		1/50 (2%)	
		1/48 (2%)				0/47 (0%)			
Overall Incidence	Total	7/198 (3.54%)	Mean 3.52%	SD 2.99%	Total	2/146 (1.37%)	Mean 1.35%	SD 1.17%	
.....									
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
		9/50 (18%)	7/50 (14%)	8/50 (16%)		4/49 (8%)		5/50 (10%)	
		6/48 (13%)				2/47 (4%)			
Overall Incidence	Total	30/198 (15.15%)	Mean 15.12%	SD 2.39%	Total	11/146 (7.53%)	Mean 7.47%	SD 2.93%	
.....									
*Thyroid Gland: Follicular Cell: Adenoma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/49 (0%)		0/50 (0%)	
		0/48 (0%)				0/47 (0%)			
Overall Incidence	Total	2/198 (1.01%)	Mean 1%	SD 2%	Total	0/146 (0%)	Mean 0%	SD 0%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)		0/50 (0%)	
		0/48 (0%)				1/47 (2%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/146 (0.68%)	Mean 0.71%	SD 1.23%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/49 (0%)		0/50 (0%)	
		0/48 (0%)				1/47 (2%)			
Overall Incidence	Total	2/198 (1.01%)	Mean 1%	SD 2%	Total	1/146 (0.68%)	Mean 0.71%	SD 1.23%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: FEED

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		Male				Female			
#Tissue NOS:									
Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Tissue NOS:									
Paraganglioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Tongue:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Tongue:									
Squamous Cell Carcinoma or Papilloma Squamous									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Tongue:									
Squamous Cell Papilloma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
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		Male				Female			
#Tooth:									
Adamantinoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Tooth:									
Odontoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Urinary Bladder:									
Carcinoma or Papilloma									
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Urinary Bladder:									
Hemangiosarcoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Urinary Bladder:									
Leiomyosarcoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female			
*Urinary Bladder:									
Papilloma									
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Uterus:									
Adenoma									
						0/50 (0%)		0/50 (0%)	
						1/50 (2%)			
Overall Incidence	Total				Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Uterus:									
Carcinoma									
						0/50 (0%)		0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Uterus:									
Deciduoma Benign									
						0/50 (0%)		0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Uterus:									
Hemangioma									
						0/50 (0%)		0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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	Male	Female
#Uterus:		
Hemangiosarcoma		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	
Overall Incidence	Total 0/150 (0%)	Mean 0% SD 0%
.....		
#Uterus:		
Leiomyosarcoma		
	0/50 (0%)	1/50 (2%)
	0/50 (0%)	
Overall Incidence	Total 1/150 (0.67%)	Mean 0.67% SD 1.15%
.....		
#Uterus:		
Polyp Stromal		
	10/50 (20%)	14/50 (28%)
	10/50 (20%)	
Overall Incidence	Total 34/150 (22.67%)	Mean 22.67% SD 4.62%
.....		
#Uterus:		
Sarcoma		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	
Overall Incidence	Total 0/150 (0%)	Mean 0% SD 0%
.....		
#Uterus:		
Sarcoma Stromal		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	
Overall Incidence	Total 0/150 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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		Male				Female						
#Uterus:												
Sarcoma Stromal or Polyp Stromal												
		10/50 (20%)		14/50 (28%)								
		10/50 (20%)										
Overall Incidence		Total	34/150 (22.67%)	Mean	22.67%	SD	4.62%					
.....												
#Uterus:												
Schwannoma Malignant												
		0/50 (0%)		0/50 (0%)								
		0/50 (0%)										
Overall Incidence		Total	0/150 (0%)	Mean	0%	SD	0%					
.....												
#Vagina:												
Polyp												
		0/50 (0%)		0/50 (0%)								
		0/50 (0%)										
Overall Incidence		Total	0/150 (0%)	Mean	0%	SD	0%					
.....												
#Vagina:												
Sarcoma												
		0/50 (0%)		0/50 (0%)								
		0/50 (0%)										
Overall Incidence		Total	0/150 (0%)	Mean	0%	SD	0%					
.....												
#Zymbal's Gland:												
Adenoma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
		0/50 (0%)					0/50 (0%)					
Overall Incidence	Total	0/200 (0%)	Mean	0%	SD	0%	Total	0/150 (0%)	Mean	0%	SD	0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
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		Male				Female			
#Zymbal's Gland:									
Carcinoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Zymbal's Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied